REMARKS

1. Applicant thanks the Examiner for his detailed findings and conclusions.

2. It should be appreciated that the Applicant has elected to amend Claims 1, 15, 17, 25, 28, and 33 and to cancel Claim 31 solely for the purpose of expediting the patent process in a manner consistent with the PTO's Patent Business Goals, 65 Fed. Reg. 54603 (9/8/00). In making such amendments, Applicant has not and does not in any way narrow the scope of protection to which the Applicant considers the invention herein entitled. Rather, Applicant reserves Applicant's right to pursue such protection at a later point in time and merely seeks to pursue protection for the subject matter presented in this submission.

Hilton Davis / Festo Statement

The amendments herein to Claims 1, 15, 17, 25, 28, and 33 were not made for any reason related to patentability. Claim 1 was amended to clarify patentability only under 35 U.S.C. § 101. Claims 25 and 28 were amended to conform with standard claim drafting practices. Claims 15, 17, and 33 were amended into independent form in the absence of any 35 U.S.C. § 102 or 35 U.S.C. § 103 rejection. All of the above listed amendments were made for reasons other than patentability.

3. Claims 1-6, 8-17, 21-26, and 29-33 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1-6, 8-17, 21-26, and 29-33

As to Claims 1-6, 8-17, 21-26, and 29-33 the Applicant respectfully disagrees. However, in order to expedite the patent prosecution process, the Applicant amends Claim 1 in two places to provide clear U.S.C. § 101 support. First, the Applicant amends the preamble to require that the method is a computer

implemented method. Second, the Applicant amends Claim 1 to require that the step of measuring is performed using a glucose concentration analyzer. Support for the amendment is found in the application as filed at least within original Claim 25 and previously presented Claim 28. The Applicant notes that specific types of glucose concentration analyzers were previously presented in Claims 25 and 28 and that no U.S.C. § 101 of either Claim 25 or 28 was cited by the Examiner. Accordingly, the current rejection of Claim 1 and all claims dependent therefrom under 35 U.S.C. § 101 as being directed to non-statutory subject matter is deemed to be overcome.

4. As a result of amendments to Claim 1, the Applicant amends Claims 25 and 28 to conform descendent language with antecedent basis and to conform with standard claim drafting practices.

5. Claims 1-6, 8-17, 21-26, and 28-33 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claim 1

Claim 1 is objected to by the Examiner (1) for the use of the term "normal" in view of the phrase including the word "disorder" and (2) for the use of the term pre-diabetic.

As to the first point, the Applicant amends Claim 1 to remove the term "normal". As to the second point, the Applicant respectfully disagrees. The term pre-diabetic is well known in the field of diabetes as meaning impaired glucose tolerance. Indeed, in the application as filed at page 4 beginning at line 26 is a section defining impaired glucose tolerance, of which the first five lines are reproduced below, emphasis added.

page 4, lines 26-31:

> IMPAIRED GLUCOSE TOLERANCE
>
> It is estimated that eleven percent of the American public has this condition. Impaired glucose tolerance may be viewed as an intermediate condition between normal glucose metabolism and type II diabetes. **Impaired glucose tolerance, also known as pre-diabetes, is a condition in which blood sugar levels are higher than normal,** but do not meet the diagnostic criteria for diabetes.

The cited section clearly defines pre-diabetes as a condition having elevated blood glucose concentrations that do not yet meet the diagnostic criteria for diabetes. Hence, the term pre-diabetic is deemed to be clear, concise, well-known, and defined in the specification. Accordingly, the current rejection of Claim 1 and all claims dependent therefrom under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention is deemed to be overcome.

6. The Applicant notes that Claims 15, 17, 31, and 33 only stand rejected under U.S.C. § 101 and U.S.C. § 112, second paragraph. Hence, if the above described responses to the rejections cited under U.S.C. § 101 and U.S.C. § 112, second paragraph, are accepted by the Examiner, the Applicant notes that pending Claims 15, 17, 31, and 33 would be in allowable format if rewritten in independent form.

7. Claims 1-6, 8-13, 16, and 21-27 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. patent no. 6,925,393 (hereinafter "Kalatz").

Claims 1-6, 8-13, 16, and 21-26

Respectfully, the Applicant disagrees. However, to expedite the patent prosecution process, the Applicant amends into Claim 1 material previously examined by the Examiner and not rejected under any section of U.S.C. § 102 or

U.S.C. § 103. Particularly, the Applicant amends into Claim 1 all elements of Claim 31, where current Claim 31 has no pending rejections under any section of U.S.C. § 102 or U.S.C. § 103. Claim 31 was only rejected under U.S.C. § 112, which was addressed, *supra*. Accordingly, the current rejection of Claims 1-6, 8-13, 16, and 21-26 under 35 U.S.C. § 102(e) as being anticipated by Kalatz is deemed to be overcome.

Claim 27

The Applicant notes that Claim 27 was previously cancelled from the application.

8. The Applicant cancels Claim 31 from the application.

9. Claim 1 stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. patent no. 6,518,069 (hereinafter "Otvos").

The Applicant notes that only Claim 1 stands rejected under Otvos. However, the current office action describes anticipation arguments of Claims 1-6, 16, 22-24, 28-30, and 32. Hence, in order to facilitate rapid prosecution of the current application in a manner consistent with the PTO's Patent Business Goals, 65 Fed. Reg. 54603 (9/8/00), the Applicant proceeds as if the Examiner had rejected all of Claims 1-6, 16, 22-24, 28-30, and 32 as being anticipated by Otvos.

In view of the above described amendments to Claim 1, the current rejection of Claims 1-6, 16, 22-24, 28-30, and 32 under 35 U.S.C. § 102(e) as being anticipated by Otvos is rendered moot.

10. Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kalatz in further view of U.S. patent no. 6,853,854 (hereinafter "Proniewicz").

In view of the above described amendments to Claim 1, the current rejection of Claim 25 under 35 U.S.C. § 103(a) as being unpatentable over Kalatz in further view Proniewicz is rendered moot.

11. The applicant rewrites Claims 15, 17, and 33 in independent form incorporating all elements of parent Claim 1 and all intervening claims. Again, the Applicant note that Claims 15, 17, and 33 have no pending rejections under any section of 35 U.S.C. § 102 or 35 U.S.C. § 103 and that all rejections under sections of 35 U.S.C. § 101 and 35 U.S.C. § 112 are addressed, *supra.*

12. The Examiner objects to the specification as containing hyperlinks.

The Applicant amends the specification at page 8, lines 7-24; page 3, lines 12-17; page 6, lines 3-7; and page 7, lines 29-32 to remove all hyperlinks for the specification. Accordingly, the current objection to the specification as containing hyperlinks is deemed to be overcome.

13. The above described amendments to parent Claim 1 added additional limitations not found in copending patent application no. 10/702,710. Therefore, the provisional obviousness type double patenting rejection is rendered moot.

14. Regarding the minor informalities noted by the Examiner, Applicant submits herewith a replacement response for the response filed 10/11/2006, in which the Applicant correctly references serial no. 10/702,236.

CONCLUSION

In view of the above, the Application is deemed to be in allowable condition. The Examiner is therefore earnestly requested to withdraw all outstanding objections and rejections, allowing the Application to pass to issue as a United States Patent. Should the Examiner have any questions regarding the application, he is respectfully urged to contact Applicant's attorney at (650) 474-8400.

Respectfully submitted,

Michael A. Glenn
Reg. No. 30,176

Customer No. 22,862

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Hetzel
Docket No.: SENS0002
Serial No.: 10/702,236
Art Unit: 1631
Filed: November 5, 2003
Examiner: SIMS, Jason M.
Title: A METHOD OF SCREENING FOR DISORDERS OF GLUCOSE METABOLISM

October 11, 2006

MAIL STOP AMENDMENT
Commissioner for Patents
PO BOX 1450
Alexandria, VA 22313-1450

AMENDMENT

An Amendment in response to the Office Action dated July 11, 2006 in the above-named case is provided.

The Application is amended as follows:

- Claims 1-6, 8, 9, 12, 16, 17, and 21-25 are amended;
- Claims 7, 18-20, and 27 are cancelled from the Application; and
- new Claims 28-33 are added to the Application.

Amendments to the Claims begin at sheet #2 of this paper, remarks begin at sheet #9.

The Commissioner is authorized to charge any fees that may be due and to credit any overpayments to Deposit Account 07-1445, Glenn Patent Group.

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method for ~~of~~ screening a subject for disorders of glucose metabolism, comprising steps of:

measuring a glucose concentration profile, said glucose concentration profile comprising a plurality of blood glucose concentrations from at least after a glucose or meal challenge;

generating a screening factor, wherein said screening factor comprises a mathematical representation of at least a plurality of glucose concentrations within said glucose concentration profile, wherein said screening factor is uniquely associated with a state of glucose metabolism disorder, wherein said state of glucose metabolism disorder comprises any of:

diabetic,

pre-diabetic;

normal; and

hyperinsulinemic;

~~using at least a portion of said plurality of blood glucose values, evaluating a shape of said profile according to at least one parameter of said profile;~~ and

classifying the ~~said~~ subject into ~~at least~~ one of said states of glucose metabolism disorder ~~predetermined class~~ based on evaluation of said ~~shape~~ screening factor.

2. (Currently Amended) The method of Claim 1, wherein said plurality of blood glucose concentrations ~~values~~ comprises a time series.

3. (Currently Amended) The method of Claim 1, wherein said blood glucose concentrations ~~values~~ comprise ~~are~~ actual values.

4. (Currently Amended) The method of Claim 1, wherein said blood glucose concentrations ~~values~~ comprise ~~are~~ relative values.

5. (Currently Amended) The method of Claim 1, wherein said screening factor is generated using a parameter, wherein said parameters includes any of:

~~initial fasting glucose concentration;~~

maximum glucose concentration;

glucose concentration after elapse of a predetermined time interval;

area under the curve of the glucose profile; and

area under the curve of the glucose profile over a defined period of time.

6. (Currently Amended) The method of Claim 5, wherein said classifying ~~evaluating~~ step comprises:

comparing ~~any of~~ said screening factor ~~parameters~~ with a corresponding predetermined values and/or a ranges of values indicative of either a normal condition or one of a plurality of abnormal conditions.

7. (Cancelled)

8. (Currently Amended) The method of Claim 1, wherein said generating ~~evaluation~~ step comprises:

determining a weight for each of a set of ~~said~~ parameters.

9. (Currently Amended) The method of Claim 8, wherein said step of determining a weight comprises assigning each of said set of parameters a value on either a linear or non-linear scale~~, according to value of said parameter, said assigned value comprising said weight~~.

10. (Original) The method of Claim 9, wherein minimum and maximum of said scale correspond to predetermined threshold values for a normal condition and a diabetic condition, respectively.

11. (Original) The method of Claim 9, wherein minimum and maximum of said scale correspond to predetermined threshold values for a low glucose tolerance and a normal condition, respectively.

12. (Currently Amended) The method of Claim 9, wherein maximum of said scale corresponds to predetermined threshold values for a diabetic condition.

13. (Original) The method of Claim 9, wherein ranges of values represented by said scale are established according to standard diagnostic criteria.

14. (Original) The method of Claim 9, wherein missing parameters are assigned a weight of zero.

15. (Original) The method of Claim 9, wherein missing data are supplied from historical data.

16. (Currently Amended) The method of Claim ~~19~~, wherein said ~~further comprising a~~ step of generating ~~calculating one or more~~ a screening factors uses ~~based on~~ actual or relative values for ~~of said~~ parameters and ~~said~~ weights.

17. (Currently Amended) The method of Claim 16, wherein said step of generating a ~~calculating~~ screening factors comprises the step of calculating a weighted average of ~~said~~ weighted parameters according to:

$$SF = \frac{(P_1W_1 + P_2W_2 + P_3W_3 + P_4W_4 + P_5W_5 + P_6W_6)}{(W_1 + W_2 + W_3 + W_4 + W_5 + W_6)}$$

wherein ~~SF = said screening factor~~ *SF* is said screening factor, P_1 is a first parameter, said first parameter comprising glucose concentration, P_2 is a second parameter, said second parameter comprising rate at which glucose concentration rises, P_3 is a third parameter, said third parameter comprising maximum monitored glucose concentration; P_4 is a fourth parameter, said fourth parameter comprising duration that glucose remains elevated; P_5 is a fifth parameter, said fifth parameter comprising rate of decrease of glucose concentration after a peak; and P_6 is a sixth parameter, said sixth parameter comprising minimum glucose concentration after a maximum; and wherein W_1, W_2, W_3, W_4, W_5, W_6, are weighting factors, wherein at least two of said weighting factors are non-zero.

18. (Cancelled)

19. (Cancelled)

20. (Cancelled)

21. (Currently Amended) The method of Claim 16, further comprising a step of establishing threshold screening limits based on said screening factors.

22. (Currently Amended) The method of Claim 1, wherein said mathematical representation is generated using ~~parameters include~~ any of:

an initial fasting glucose concentration;

a rate of increase of glucose concentration following said glucose challenge;

a peak monitored glucose concentration;

a duration glucose remains elevated;

a rate of decrease of glucose concentration following said peak concentration;

a minimum glucose concentration following said peak concentration;

an area under the curve for the glucose profile; and

an area under the curve during a subset in time of the glucose profile.

23. (Currently Amended) The method of Claim 1, further comprising the step of advising the ~~said~~ subject of screening results.

24. (Currently Amended) The method of Claim 1, further comprising the step of advising the ~~said~~ subject of health risks from complications likely to result from subject's condition.

25. (Currently Amended) The method of Claim 1, wherein said blood glucose concentrations ~~values~~ are obtained using any of:

~~a noninvasive blood glucose analyzer;~~

a minimally invasive blood glucose analyzer; and

an invasive blood glucose analyzer.

26. (Original) The method of Claim 1, wherein a processing device so programmed executes said steps.

27. (Cancelled)

28. (New) The method of Claim 1, wherein said blood glucose concentrations are obtained using a noninvasive blood glucose analyzer.

29. (New) The method of Claim 1, wherein said screening factor comprises a numerical value.

30. (New) The method of Claim 1, wherein said screening factor comprises representation of a shape of said glucose concentration profile.

31. (New) The method of Claim 1, wherein said screening factor comprises an abstract representation of said glucose concentration profile.

32. (New) The method of Claim 1, wherein said screening factor comprises the result of an unsupervised classification.

33. (New) The method of Claim 1, wherein said screening factor comprises the result of a supervised classification.

REMARKS

1. Applicant thanks the Examiner for his findings and conclusions.

2. It should be appreciated that the Applicant has elected to amend Claims 1-6, 8, 9, 12, 16, 17, and 21-25 and to cancel Claims 7, 18-20, and 27 solely for the purpose of expediting the patent process in a manner consistent with the PTO's Patent Business Goals, 65 Fed. Reg. 54603 (9/8/00). In making such amendments, Applicant has not and does not in any way narrow the scope of protection to which the Applicant considers the invention herein entitled. Rather, Applicant reserves Applicant's right to pursue such protection at a later point in time and merely seeks to pursue protection for the subject matter presented in this submission.

Hilton Davis / Festo Statement

The amendments herein were not made for any reason related to patentability. Claims 1-6, 8, 9, 12, 16, 17, and 21-24 were amended to clarify the invention. Claim 25 was separated into two claims. All of the above listed amendments were made for reasons other than patentability.

3. Claims 1-22 and 25-27 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1-22 and 25-27

The Applicant amends Claim 1 in order to clarify that the invention has a useful result by further requiring that the step of classifying the subject classifies the subject into a state of glucose metabolism disorder. Support for the amendment is found in the Application as filed at least at page 11, lines 3-17; page 4, lines 25-30; and page 5, lines 11-13. Screening a subject for any biomedical disorder is a useful result as evidenced by a multi-billion dollar field devoted to testing for

medical disorders. In this case, Claim 1 as amended is still more specific requiring the useful result of classifying a subject into a state of metabolism disorder, such as being diabetic, pre-diabetic, normal, or being hyperinsulinemic. Accordingly, the rejection of Claims 1-22 and 25-27 under 35 U.S.C. § 101 as being directed to non-statutory subject matter is deemed to be overcome.

4. Claims 1-27 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claim 1

As to Claim 1, the Examiner states the term "shape" is vague and indefinite. The Applicant amends Claim 1 in order to remove the term shape from Claim 1. Accordingly, the rejection of Claim 1 and all claims dependent therefrom under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention is deemed to be overcome.

Claim 1

Claim 1 is objected to by the Examiner as having improper antecedent basis for the clauses "said plurality of glucose values" and "said profile". For both cases, the Applicant amends Claim 1 to remove the cited clauses. Accordingly, the rejection of Claim 1 and all claims dependent therefrom under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention is deemed to be overcome.

Claims 17-20

The Applicant amends Claim 17 in order to clarify the invention by further defining P_1 as a first parameter, the first parameter comprising glucose

concentration, P_2 as a second parameter, the second parameter comprising rate at which glucose concentration rises, P_3 as a third parameter, the third parameter comprising maximum monitored glucose concentration; P_4 as a fourth parameter, the fourth parameter comprising duration that glucose remains elevated; P_5 as a fifth parameter, the fifth parameter comprising rate of decrease of glucose concentration after a peak; and P_6 as a sixth parameter, the sixth parameter comprising minimum glucose concentration after a maximum; and wherein W_1, W_2, W_3, W_4, W_5, W_6, are weighting factors, wherein at least two of said weighting factors are non-zero. Further, in order to expedite the patent prosecution process, the Applicant cancels Claims 18-20. Accordingly, the rejection of Claims 17-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention is deemed to be overcome.

5. Claims 1-13, 16, and 21-27 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. patent no. 6,925,393 (hereinafter "Kalatz").

The Applicant amends Claim 1 in order to distinguish Claim 1 from the cited art by further requiring Claim 1 to generate a screening factor where the screening factor comprises a mathematical representation of at least a plurality of glucose concentrations within the glucose concentration profile, where the screening factor is uniquely associated with a state of glucose metabolism disorder, and where the state of glucose metabolism disorder includes any of: diabetic, pre-diabetic, normal, and hyperinsulinemic. Still further, the Applicant amends Claim 1 to clarify that the classifying step classifies the subject into one of the states of glucose metabolism disorder based on evaluation of the screening factor. Support for the amendment is found in the specification as filed at least at page 9, lines 1-7, 9-11, and 23; Figure 2; and page 11, lines 3-17; page 4, lines 25-30; page 5, lines 11-13; and page 25, line 4 to page 26, line 31. In stark contrast, Kalatz does not teach or suggest the use of a screening factor used to classify a subject into a state of metabolism disorder where the metabolism disorder is any of diabetic, pre-diabetic, normal, and hyperinsulinemic. Accordingly, the rejection

of Claims 1-13, 16, and 21-27 under 35 U.S.C. § 102(e) as being anticipated by Kalatz is deemed to be overcome.

The Applicant further amends Claim 1 to correct a grammatical error in the preamble and to clarify that the glucose profile is a glucose concentration profile.

As a result of amendments to parent Claim 1, the Applicant amends Claims 2-6, 8, 9, 12, 17, and 21-24 as detailed, *infra*.

Claims 2-4

The Applicant amends Claims 2-4 to conform descendent language with antecedent language usage and further amends Claims 3 and 4 in order to conform with standard claim drafting practices.

Claims 5, 6, 8, 9, 16, 17, 21, and 22

The Applicant amends Claims 5, 6, 8, 9, 16, 17, 21, and 22 to conform language usage with that of amended Claim 1 according to standard claim drafting practices.

Claims 16 and 17

The Applicant further amends Claims 16 and 17 to depend directly from parent Claim 1.

Claims 12, 23, and 24

The Applicant amends Claims 12, 23, and 24 to conform with standard claim drafting practices.

Claim 7

The Applicant cancels Claim 7 from the Application.

6. Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kalatz in view of U.S. patent no. 6,853,854 (hereinafter "Proniewicz").

In view of the above described amendments, the current rejection of Claim 25 under 35 U.S.C. § 103(a) as being unpatentable over Kalatz in view of Proniewicz is rendered moot.

7. Claims 1 and 27 stand provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of Claim 1 of copending patent application no. 10/702,710. As amended, Claim 1 is no longer coextensive in scope with that of Claim 1 of copending patent application no. 10/702,710. Claim 27 is cancelled from the Application. Accordingly, the rejection of Claims 1 and 27 under 35 U.S.C. § 101 as claiming the same invention as that of Claim 1 of copending patent application no. 10/702,710 is deemed to be overcome.

8. The Applicant amends Claim 25 and adds new Claim 28 to separate the claim elements into two claims and to conform descendent language with antecedent language usage according to standard claim drafting practices. Support for new Claim 28 is found at least within original Claim 25.

9. New Claims 29-33 are added to the Application. Support for new Claims 29-33 is found in the Application as filed at least at page 9, lines 9-11; page 16, lines 12-22; page 22, line 25 to page 23, line 21; and page 25, line 30 to page 26, line 14. The Applicant certifies that no new matter was added by way of the new Claims.

CONCLUSION

In view of the above, the Application is deemed to be in allowable condition. The Examiner is therefore earnestly requested to withdraw all outstanding rejections, allowing the Application to pass to issue as a United States Patent. Should the Examiner have any questions regarding the application, he is respectfully urged to contact Applicant's attorney at (650) 474-8400.

Respectfully submitted,

Michael A. Glenn
Reg. No. 30, 176

Customer No. 22,862